K030260

Section 11 Summary of 510(k) Submission

FEB 2 0 2003

11.1 Type of Submission

Special 510(k)
Date of Submission: January 9, 2003

11.2 Manufacturer

VascuMetrix, LLC
1058 N. Higley Rd.
Suite 204
Mesa, AZ 85205
(480) 807-6300
Fax: (480) 807-6307

Establishment Registration Number: 2032423
Owner/Operator Number: 9046947

11.3 Contact Person

Nick Raible
President

11.4 Device

510(k) Number:	Not yet assigned
Proprietary Name:	Gelbfish Flex Vascular Dilator
Generic Name:	Dilator, Vessel, For Percuteneous Catheterization
Classification:	Class II
Relevant Section:	870.1310
Product Code:	DRE
Intended Use:	These devices are intended to be used over a guidewire to dilate or calibrate blood vessels.

11.5 Predicate Device

510(k) Number:	K012256
Proprietary Name:	Gelbfish Vascular Dilators
Generic Name:	Dilator, Vessel, For Percuteneous Catheterization
Classification:	Class II
Relevant Section:	870.1310
Product Code:	DRE
Intended Use:	These devices are intended to be used over a guidewire to dilate or calibrate blood vessels.

11.6 Comparison to Predicate Device

1. The original 510(k) on these dilators limited the shaft material to stainless steel. The modified device has a polyurethane shaft.

2. The original device uses laser welding to bond the tip to the shaft. The modified device will use a medical grade adhesive to bond the tip to the shaft.

11.7 Conclusion

Comparison of the original device with the modified device for physical properties, performance characteristics and intended use, indicate that these devices are substantially equivalent and that there are no additional safety issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2003

Mr. Nick Raible
President
VascuMetrix, LLC
1058 N Higley Rd., Suite 204
Mesa, AZ 85205

Re: K030260
Trade/Device Name: Gelbfish Flex Vascular Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catherterization
Regulatory Class: Class II
Product Code: DRE
Dated: January 8, 2003
Received: January 24, 2003

Dear Mr. Raible:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030260

Device Name: Gelbfish FlexVascular Dilator

Indications For Use:

Section 2 Statement of Indented Use

These devices are intended to be used over a guidewire to dilate or calibrate blood vessels.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030260

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____